Provider Rule Interpretation 99-1(u): EMS Pharmaceutical Storage and Maintenance

Original written March 1999
Updated March 2005

Background:
A Public Health Advisory – Storage of Drugs and Medical Devices prompted the policy.
The Texas Food Drug and Cosmetic Act states that drug or medical device is deemed adulterated if it is stored under conditions that result in the product's safety or effectiveness being compromised. Drugs and medical devices that are stored in places that do not have proper environmental controls may become ineffective or dangerous. Products that are stored improperly in vehicles (i.e. ambulances, personal vehicles) are considered adulterated products and unsafe for human use. Guidelines for the proper storage of drugs and medical devices are generally recommended by the manufacturer of the product. Where no guidelines are listed on drug labels, the United States Pharmacopoeia recommends that products are stored at room temperature, away from humidity, and where necessary, away from light. For those devices that are not labeled with storage requirements, care should be taken to avoid extremes of temperature, humidity and light. All labels should be read and checked prior to storage. It is the responsibility of the operator to make sure that proper storage requirements are met. The Texas Department of State Health Services has the authority to detain and take action against those products that do not meet storage criteria.

Rule Reference: 25TAC 157.11

General:
The current policy contains the wording "parenteral" pharmaceuticals". By removing the word "parenteral" the policy would apply to all pharmaceuticals.

Interpretation:
The EMS provider licensure or relicensure applicant shall provide evidence of an operational policy which shall list the pharmaceuticals authorized by the medical director and which shall define the storage and maintenance procedures for each in accordance with the manufacturers and/or FDA recommendations. Compliance with the policy shall be incorporated into the provider's Quality Management process and shall be documented on the unit readiness reports.

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